

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Liat Hayardeny, et al.  
U.S. Serial No. : 10/591,195  
Filed : as §371 national stage of PCT  
International Application No.  
PCT/US2005/007072, filed March 3,  
2005  
For : COMBINATION THERAPY WITH GLATIRAMER  
ACETATE AND RILUZOLE

1185 Avenue of the Americas  
New York, New York 10036  
February 8, 2008

Mail Stop PCT  
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P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following Reference Items 1-61 which are listed again on the accompanying Form PTO-1449 (**Exhibit A**). Applicants request that the Examiner review the references and make them of record in the subject application.

This Information Disclosure Statement is being submitted before the issuance of a first Office Action on the merits in connection with the subject application. Accordingly, no fee is required and this Information Disclosure Statement shall be considered pursuant to 37 C.F.R. §1.97(b)(3).

Reference items 1-27 are either U.S. patents or U.S. patent application publications. Pursuant to 37 C.F.R. 1.98(a)(2), copies of references 1-27 are not being submitted.

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Copies of the below listed references 28-61 are attached hereto as  
**Exhibits 1-34**, respectively.

1. U.S. Patent No. 5,800,808, issued September 1, 1998  
(Konfino, et al.);
2. U.S. Patent No. 5,981,589, issued November 9, 1999  
(Konfino, et al.);
3. U.S. Patent No. 6,048,898, issued April 11, 2000  
(Konfino, et al.);
4. U.S. Patent No. 6,054,430, issued April 25, 2000  
(Konfino, et al.);
5. U.S. Patent No. 6,214,791, issued April 10, 2001  
(Arnon, et al.);
6. U.S. Patent No. 6,342,476, issued January 29, 2002  
(Konfino, et al.);
7. U.S. Patent No. 6,362,161, issued March 26, 2002  
(Konfino et al.);
8. U.S. Patent No. 6,514,938, issued February 4, 2003 (Gad  
et al.);
9. U.S. Patent No. 6,620,847, issued September 16, 2003  
(Konfino, et al.);
10. U.S. Patent No. 6,800,285, issued October 5, 2004  
(Rodriguez);

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11. U.S. Patent No. 6,800,287, issued October 5, 2004 (Gad et al.);
12. U.S. Patent No. 6,939,539, issued September 6, 2005 (Konfino, et al.);
13. U.S. Patent No. 7,022,663, issued April 4, 2006 (Gilbert et al.);
14. U.S. Patent No. 7,033,582, issued April 25, 2006 (Yong, et al.);
15. U.S. Patent No. 7,074,580, issued July 22, 2006 (Gad et al.);
16. U.S. Patent No. 7,163,802 B2, issued January 16, 2007 (Gad et al.);
17. U.S. Patent No. 7,199,098, issued April 3, 2007 (Konfino, et al.);
18. U.S. Patent No. 7,279,172, issued October 9, 2007 (Aharoni et al.);
19. U.S. Patent Application Publication No. US-2003-0170729 A1, published September 11, 2003 (Klinger);
20. U.S. Patent Application Publication No. US-2005-0170004, published August 4, 2005 (Rosenberger);
21. U.S. Patent Application Publication No. US-2006-0122113, published June 8, 2006 (Pinchasi et al.);

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22. U.S. Patent Application Publication No. US-2006-0172942 A1, published August 3, 2006 (Dolitzky);
23. U.S. Patent Application Publication No. US-2006-0052586, published March 9, 2006 (Dolitzky);
24. U.S. Patent Application Publication No. US-2007-0021341 A1 published January 25, 2007 (Sela et al.);
25. U.S. Patent Application Publication No. US-2007-0021324 A1 published January 25, 2007 (Dolitzky et al.);
26. U.S. Patent Application Publication No. US-2007-0048794 A1, published March 1, 2007 (Gad et al.);
27. U.S. Patent Application Publication No. US-2007-0054857, published March 8, 2007 (Pinchasi et al.);
28. U.S. Serial No. 11/590,338, filed October 30, 2006 (Pinchasi) (**Exhibit 1**);
29. PCT International Application No. PCT/US98/00375 (WO 98/30227), published July 16, 1998 (Arnon et al.) (**Exhibit 2**);
30. PCT International Application No. PCT/US99/16747 (WO 00/05250) published February 3, 2000 (Aharoni et al.) (**Exhibit 3**);
31. PCT International Application No. PCT/US99/22402 (WO 00/18794) published April 6, 2000 (Gad, et al.) (**Exhibit 4**);

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32. PCT International Application No. PCT/US99/27107 (WO 00/27417) published May 18, 2000 (Aharoni et al.) (**Exhibit 5**);
33. PCT International Application No. PCT/US01/05198 (WO 01/60392) published August 23, 2001 (Gilbert et al.) (**Exhibit 6**);
34. PCT International Application No. PCT/US01/18248 (WO 01/93828), published December 13, 2001 (Yong et al.) (**Exhibit 7**);
35. PCT International Application No. PCT/US01/19649 (WO 01/97846) published December 27, 2001 (Rodriguez and Ure) (**Exhibit 8**);
36. PCT International Application No. PCT/US02/38859 (WO 03/048735), published June 12, 2003 (Klinger) (**Exhibit 9**);
37. Bornstein et al., "Treatment of MS with a Synthetic Polypeptide: Preliminary Results" Ann. Neurol., 1980, 8, 117 (**Exhibit 10**);
38. Bornstein et al., "Treatment of MS with synthetic polypeptide: preliminary results" Trans. Am. Neurol. Assoc., 1980, 105, 348-350 (**Exhibit 11**);
39. Bornstein et al., "MS: Trial of a synthetic polypeptide" Ann. Neurol., 1982, 11, 317-319 (**Exhibit 12**);
40. Bornstein et al., "Clinical trials of Copolymer 1 in

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MS" Ann. N.Y. Acad. Sci. (USA), 1984, 366-372 (**Exhibit 13**);

41. Bornstein et al., "Clinical Trials of a synthetic polypeptide (Copolymer 1) for the treatment of MS" Immunol. & Clin. Aspects of MS, 1984, 144-150 (**Exhibit 14**);
42. Bornstein et al., "MS: Clinical Trials of a Synthetic Polypeptide, Copolymer 1" Neurol., 1985, 35 (Suppl. 1), 103 (**Exhibit 15**);
43. Bornstein, "Cop 1 may be beneficial for patients with exacerbating remitting form of MS" Adv. Ther., 1987, 4, 206 (**Exhibit 16**);
44. Bornstein, et al., "A Pilot trial of Cop 1 in Exacerbating remitting MS" New Eng. J. Med., 1987, 317 (7), 408-414 (**Exhibit 17**);
45. Bornstein, et al., "Clinical Experience with COP-1 in MS" Neurol., 1988, 38 (Suppl. 2.), 66-69 (**Exhibit 18**);
46. Bornstein, et al., "Rationale for Immunomodulating Therapies of MS" Neurol., 1988, 38 (Suppl. 2.), 80-81R (**Exhibit 19**);
47. Bornstein et al., "Pilot Trial of COP-1 in Chronic Progressive MS: Preliminary report" Intl. MS Conf.1988, in Elsevier Sci. Publi. 1989, 225-232 (**Exhibit 20**);
48. Bornstein et al., "Clinical Trials of Cop 1 in MS"

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Handbook of MS, 1990, 469-480 (**Exhibit 21**);

49. Bornstein et al., "A Placebo-controlled, Double-Blind, Randomized Two-center, Pilot Trial of Cop 1 in Chronic Progressive MS" *Neurol.*, 1991, 41, 533-539 (**Exhibit 22**);
50. Bornstein et al., "Treatment of MS with Copolymer 1" *Treatmt. of MS, Trial Design.*, 1992, 173-198US5,800,808 (**Exhibit 23**);
51. Bornstein, "Clinical Experience: Hopeful Prospects in MS," *Hosp Prac. (Off. Ed.)* May 15, 1992 vol. 27 (No. 5) L135-138, 141-142, 145-158 (**Exhibit 24**);
52. Kalkers et al., "The effect of the neuroprotective agent riluzole on MRI parameters in primary progressive multiple sclerosis: a pilot study" in *Multiple Sclerosis*, 2002, vol. 8, issue 6, pages 532-533 (**Exhibit 25**);
53. Sela et al., "Glatiramer acetate in the treatment of multiple sclerosis" in *Expert Opin. Pharmacother.*, 2001, vol.2, no.7, pages 1149-1165 (**Exhibit 26**);
54. Copaxone® (glatiramer acetate injection), prescribing information,  
<http://www.copaxone.com/pdf/PrescribingInformation.pdf> (**Exhibit 27**);
55. International Preliminary Report on Patentability issued by the International Bureau of WIPO dated

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December 24, 2007 in connection with International Application No. PCT/US2005/0007072 (**Exhibit 28**);

56. PCT International Search Report issued November 30, 2007 for International Application Publication No. PCT/US2005/0007072 (**Exhibit 29**);
57. Written Opinion of the International Searching Authority issued by the International Searching Authority (ISA/AU) on November 30, 2007 in connection with International Application No. PCT/US2005/0007072 (**Exhibit 30**);
58. "COPAXONE®" in Physician's Desk Reference, Medical Economics Co., Inc., Montvale, NJ, 2002, 3115 (**Exhibit 31**);
59. PCT International Application No. PCT/CA2003/001744 (WO 04/43995), published May 27, 2004 (Bejan et al.) (**Exhibit 32**);
60. PCT International Application No. PCT/US2005/039003 (WO 06/50122), published May 11, 2006 (Ray et al.) (**Exhibit 33**); and
61. PCT International Application No. PCT/US2007/072865 (WO 08/06026), published January 10, 2008 (Iyer et al.) (**Exhibit 34**).

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If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone at the number provided below.

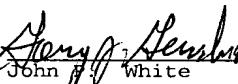
No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



John P. White  
Registration No. 28,678  
Gary J. Gershik  
Registration No. 39,992  
Attorneys for Applicants  
Cooper & Dunham LLP  
1185 Avenue of the Americas  
New York, New York 10036  
(212) 278-0400

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Reg. No. 28,678  
Gary J. Gershik  
Reg. No. 39,992